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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,257	01/20/2003	Francois Bertelli	A0000179/2-01-MG	9390

7590 06/28/2006

Mehdi Ganjeizadeh
Warner Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,257	BERTELLI ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Note: It is noted that the Examiner has interpreted claims 10-21 as method claims.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9 and 22 drawn to a method for the screening of ligands binding a cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$-1 subunit.

Group II, claim(s) 10-14, drawn to a method for the purification and screening of $\alpha_2\delta$-1 using tagged peptide sequences.

Group III, claim(s) 15-19, drawn to a method for the purification and screening of $\alpha_2\delta$-1 using nucleic acids encoding tagged sequence.

Group IV, claim(s) 20-21, drawn to a method for the screening of $\alpha_2\delta$-1 using labeled compounds.

Group V, claim(s) 23-24 drawn to a kit for screening of ligands which bind a cerebral cortical voltage-dependent channel $\alpha_2\delta$-1 subunit.

Group VI, claim(s) 25-28 drawn to a method for the screening of ligands binding a cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$ subunit.

Group VII, claim(s) 29-30 drawn to a kit for screening of ligands which bind a cerebral cortical voltage-dependent channel $\alpha_2\delta$ subunit.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a binding assay for the screening of ligands which bind to a cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$-1 subunit, comprising contacting a secreted soluble $\alpha_2\delta$-1 subunit with a ligand, candidate product or a labeled compound and measuring the binding activity to $\alpha_2\delta$-1, which is not required by the other methods of Groups II-IV and VI.

Group II recites the special technical feature of purification and screening of $\alpha_2\delta$-1 using peptide sequences as tags, which is not required by the other methods of Groups I, III-IV and VI.

Group III recites the special technical feature of purification and screening of $\alpha_2\delta$-1 using nucleic acid sequences encoding the tags, which is not required by the other methods of Groups I, II, IV and VI.

Group IV recites the special technical feature of screening of $\alpha_2\delta$-1 ligands using labeled compounds having less than 500nm binding affinity for the gabapentin binding site of $\alpha_2\delta$-1, which is not required by the other methods of Groups I-III and VI.

Group V recites the special technical feature of a kit for the screening of ligands which bind to cerebral cortical voltage-dependent channel $\alpha_2\delta$-1 subunit, which is not required by the other products of Group VII.

Group VI recites the special technical feature of a binding assay for the screening of ligands which bind to a cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$ subunit, comprising contacting a secreted soluble $\alpha_2\delta$ subunit with a ligand, candidate product or a labeled compound and measuring the binding activity to $\alpha_2\delta$, which is not required by the other methods of Groups I-IV.

Group VII recites the special technical feature of a kit for the screening of ligands which bind to cerebral cortical voltage-dependent channel $\alpha_2\delta$ subunit, which is not required by the other products of Group V.

3. A further restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The applicant is required to elect *one* sequence for prosecution, from one of the following groups:

A) SEQ ID NO: 30

B) SEQ ID NO: 31

C) SEQ ID NO: 32

D) SEQ ID NO: 33

E) SEQ ID NO: 34

F) SEQ ID NO: 35

G) SEQ ID NO: 36

H) SEQ ID NO: 37

I) SEQ ID NO: 38

J) SEQ ID NO: 41

K) SEQ ID NO: 42

L) SEQ ID NO: 43

M) SEQ ID NO: 44

4. The inventions listed as Groups A-M do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, the different inventions of Groups (A-M) are unique proteins and nucleic acid molecules

of different lengths and are composed of different amino acids and base pairs. Accordingly, each of the different protein and nucleic acid sequences are not so linked under PCT Rule 13.1 and are thus placed in thirteen different inventive groups numbered A-M. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Furthermore, each of the sequences represents a different gene/protein with unique and diverse functional features.

Note: This is a Restriction requirement, not an Election of species. In order to be fully responsive, Applicant must select one from Inventions I-VII and one from groups A-M.

It is noted that SEQ ID NOs: 30-32 and 38 are nucleic acid sequences.

5. Species Election

A) Assay method

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) SPA assay

b) Flashplate assay

c) Filter binding assay

The claims are deemed to correspond to the species listed above in the following manner:

Claims 3-6 and 27-28

The following claim(s) are generic: 1,2,7-9 and 25-26.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above assay methods are distinct having different starting materials, protocols, evaluation methods and levels of success. For example, the special technical feature of (a) is the SPA assay. This special technical feature is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

B) Peptide epitope Tag type

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

d) C-myc

e) FLAG

f) Sequence of 6 histidine residues

g) Heamaglutin A

h) V5

i) Xpress

j) GST

The claims are deemed to correspond to the species listed above in the following manner: Claims 10-19

The following claim(s) are generic: 10, 11, 15 and 16
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above epitope tags have different nucleic acid and amino acid sequences, bind to distinct and specific antibodies and are used in different detection and purification assay procedures. For example, the special technical feature of (d) is a c-myc tag. This special technical feature is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

C) Labeled compound for the Gabapentin binding site

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

k) Gabapentin

l) L-Norleucine

m) L-Allo-Isoleucine

n) L-Methionine

o) L-Leucine

p) L-Isoleucine

q) L-Valine

r) L-Phenylalanine

The claims are deemed to correspond to the species listed above in the following manner: Claims 21, 24 and 30

The following claim(s) are generic: 20, 23 and 29
The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above compounds have different structure and binding affinity. For example, the special technical feature of (k) is gabapentin. This special technical feature is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. In response to this Office Action/Election requirement, applicant must elect one from Groups I-VII and A-M (amino acid/nucleic acid sequence) and must additionally elect a species of assay method, epitope tag and labeled compound for consideration.

7. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Notice of Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
20 June 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER